



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Shone *et al.*

Art Unit: *To Be Assigned*

Appl. No.: 10/527,411 (U.S. Nat'l Phase  
of PCT/GB2003/003824)

Examiner: *To be assigned*

Intl. Filing Date: September 12, 2003

Atty. Docket: 1581.0130005/RWE/ALS

For: **Recombinant Toxin Fragments**

**Information Disclosure Statement Under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

***Mail Stop: Amendment  
Art Unit 1645***

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents were cited by or submitted to the Office in Information Disclosure Statements that comply with 37 C.F.R. § 1.98(a)-(c) in Application No. 10/241,596, filed September 12, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to document AC1, which is directed to related technical subject matter. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month and/or day of publication, the year and/or month of publication of the listed document is sufficiently earlier or later than the effective U.S. filing date and any foreign priority date so that the month and/or day of publication is not in issue. Applicants have listed

publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of an Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

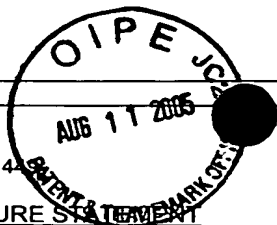
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Aaron L. Schwartz  
Attorney for Applicants  
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Date: August 11, 2005

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FORM PTO-144

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1581.0130005/RWE/ALSAPPLICANT NO.  
10/527,414 (Nat'l Phase of  
PCT/GB2003/003824)

FIRST NAMED INVENTOR

Shone *et al.*

INTL. FILING DATE:

September 12, 2003

ART UNIT

To Be Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,594,336	06/10/1986	Bizzini, B.			
	AB1	5,919,665	07/06/1999	Williams, J.A.			
	AC1	6,043,042	03/28/2000	Shone <i>et al.</i>			
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 94/21300	09/29/1994	WIPO			Yes No
	AM1	WO 94/21684	09/29/1994	WIPO			Yes No
	AN1	WO 96/12802	05/02/1996	WIPO			Yes No
	AO1	WO 96/33273	10/24/1996	WIPO			Yes No
	AP1	WO 98/07864	02/26/1998	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Binz, T., <i>et al.</i> , "The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins," <i>J. Biol. Chem.</i> 265:9153-9158, American Society for Biochemistry and Molecular Biology, Inc. (1990)
	AS	1	Bizzini, B., "Investigation of the Mode of Action of Tetanus Toxin with the Aid of Hybrid Molecules Consisting in Part of Tetanus Toxin-Derived Fragments," in <i>Bacterial Protein Toxins</i> , Academic Press London, pp. 427-434 (1984)
	AT	1	International Search Report for International Application No. PCT/GB97/02273, mailed January 30, 1998

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 98/08540	03/05/1998	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>2</u>	Kurazono, H., <i>et al.</i> , "Minimal Essential Domains Specifying Toxicity of the Light Chains of Tetanus Toxin and Botulinum Neurotoxin Type A," <i>J. Biol. Chem.</i> 267:14721-14729, American Society for Biochemistry and Molecular Biology, Inc. (1992)
	AS	<u>2</u>	Li, Y., <i>et al.</i> , "A Single Mutation in the Recombinant Light Chain of Tetanus Toxin Abolishes its Proteolytic Activity and Removes the Toxicity Seen after Reconstitution with Native Heavy Chain," <i>Biochem.</i> 33:7014-7020, American Chemical Society (1994)
	AT	<u>2</u>	Niemann, H., "Molecular Biology of Clostridial Neurotoxins," In <i>Sourcebook of Bacterial Protein Toxins</i> , Ch. 15, Alouf, J.E. and J.H. Freer, eds., Academic Press Limited, London, pp. 303-348 (1991)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Poulain, B., <i>et al.</i> , "Inhibition of transmitter release by botulinum neurotoxin A: Contribution of various fragments to the intoxication process," <i>Eur. J. Biochem.</i> 185:197-203, Springer International (1989)
	AS	<u>3</u>	Rudinger J., "Characteristics of the amino acids as components of a peptide hormone sequence," in <i>Peptide Hormones</i> , Parsons, J.A., ed., University Park Press, Baltimore, pp. 1-7 (1976)
	AT	<u>3</u>	Zhou, L., <i>et al.</i> , "Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain," <i>Biochem.</i> 34:15175-15181, American Chemical Society (November 1995)

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